

# **Glossary**

## **of Abbreviations and Terms**

**Version 2.2 – 12 May 2005**

**ICH M2**  
**Electronic Standards for the Transfer of Regulatory Information**  
**(ESTRI)**

# ICH M2

## Electronic Standards for the Transfer of Regulatory Information (ESTRI)

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### **ADR**

Adverse Drug Reaction.

### **AER**

Adverse Event Reporting.

### **ANSI**

American National Standards Institute; the first organization for fostering development of technology standards in the United States. ANSI works with industry groups and is the U.S. member to the ISO.

### **ANSI X.12**

EDI standard authored and used in USA.

### **Application**

A software program that performs a specific function.

### **Application Program Interface (API)**

A set of routines used by an application program to request or execute functions performed by the operating system or another application program.

### **Architecture**

A general term for the design and construction of computer systems, including technical infrastructure, information (data), and applications.

### **AS1 and AS2**

See EDIINT AS1 and EDIINT AS2

### **ASCII**

American Standard Code for Information Interchange. A specification for representing text as computer-readable information.

### **Authentication**

A security mechanism which verifies the identity of the sender of a message over a network.

### **Backbone**

The core, highest speed, structure of a network to which lower speed elements, or branches, are connected.

### **Biometric Signature**

A persons physical or behavioral characteristics e.g. finger, palm print, retinal scan or speed, shape and pressure of a written signature.

### **Browser**

A program which allows the user to read hypertext, to view contents of web pages, and to navigate from one page to another, e.g., Netscape Navigator, Mosaic, Microsoft Internet Explorer.

### **CA**

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Certification Authority. An agency which is trusted by a group of users of encryption technology to store and disseminate the private key of other users in the group.

#### **CCITT**

Comité Consultatif International Télégraphique et Téléphonique. CCITT publishes the X.400 and the X.500 series of standards (now known as "Telecommunications Standards Sector of the ITU").

#### **Checksum**

A fixed length code value produced from a file (or message) which is a unique representation of the precise contents of the file, such that any character or byte which is changed in the file will change the code value.

#### **CIO**

Chief Information Officer. Commonly the highest level position in a company or organization responsible for Information Technology.

#### **Client**

A computer program (or process) that requests a service of another computer program (or process), called a server. The server program may exist on the same computer or on another computer on a network.

#### **Client/Server computing**

A processing environment in which personal computers or other workstations, acting as clients, co-operate with one or more main processing units, acting as servers, to accomplish whatever tasks need to be done.

#### **Computing environment**

The set of hardware and software that enables the end-user to access IT resources.

#### **Configuration**

The way in which a computer and its peripherals (printers, modems, etc.) are connected in a system, especially the firmware (refer to definition later in glossary) settings of its internal components such as memory size and video mode.

#### **Connectivity**

The factors (hardware, software, infrastructure) which facilitate the sharing of information between one or more technical environments.

#### **Database**

One or more large structured sets of persistent data, usually associated with software to update and query the data.

#### **Database Administrator**

An individual responsible for the design and management of a database and implementation of the database management system.

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#### **Database Management System (DBMS)**

Widely used in business applications, a suite of programs which typically manage large structured sets of persistent data, offering query facilities to many users.

#### **Decryption**

To reverse encryption.

#### **Dedicated line**

A communications line that is used solely for computer connections; a telephone line leased expressly for the purpose of linking two users more-or-less permanently, generally to produce digital transmissions at a faster rate. If you buy an additional phone line for your modem, that is a dedicated line.

#### **DES**

Data Encryption Standard based on a symmetric algorithm.

#### **De facto standard**

A 'standard' which is in such widespread use that it is accepted as a standard but which has not been ratified by any official standards body, such as the ISO.

#### **DSS**

Digital Signature System. A public key system for providing digital signatures.

#### **DTD**

Document Type Definition. A hierarchical organization or representation of the information contents of a document utilized by SGML.

#### **EDI**

Electronic Data Interchange. A technology for exchanging structured information for the purpose of conducting business transactions.

#### **EDIINT**

Electronic Data Interchange – Internet Integration (an IETF specification)

#### **EDIINT - AS1**

Applicability Statement 1 is a specification for EDI communications between businesses using e-mail protocols. The AS1 standard uses Simple Mail Transfer Protocol (SMTP) to transmit data using e-mail. Security, authentication, message integrity, and privacy are assured by the use of encryption and digital signatures. Another important feature, non-repudiation, makes it impossible for the intended recipient of a message to deny having received it.

#### **EDIINT - AS2**

The specification is an extension of AS1. Applicability Statement 2 is a specification for EDI between businesses using the Internet's Web page protocol, the Hypertext Transfer Protocol (HTTP). The AS2 standard allows communication in real time rather than through e-mail delivery. Security, authentication, message integrity, and privacy are assured by the use of encryption and digital signatures.

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### **EDIFACT**

Electronic Data Interchange for Administration, Commerce and Transport. A message format standard for EDI originating from the United Nations.

### **E-mail**

Electronic mail; the service that allows users to compose, edit, send, read, forward, and store messages using mail software and word processing capability on a computer.

### **Encryption**

The process of reversibly confusing text or data using a secret formula.

### **Escrow**

To provide a copy of an encryption key to a third party (e.g. Government) for safe-keeping and so to provide access to encrypted information, with appropriate safeguards, in the case of need.

### **ESTRI**

Electronic Standards for the Transfer of Regulatory Information.

### **EWG**

Expert Working Group.

### **Firmware**

Programming that is a permanent part of a computing device.

### **Firewall**

In the context of computer security, is software that monitors files that access a network from an external source. The process uses criteria which are designed to allow access to appropriate files but which prevent unauthorized access to the net.

### **FTP**

File Transfer Protocol; a client-server protocol which allows a user of one computer to transfer files to and from another computer over a TCP/IP network.

### **Gateway**

A device or program which accepts information into a network from an external source.

### **Hardware**

The physical components of a computer system such as the system units, monitor, modem, printer, keyboard, and drives.

### **Hardware platform**

A specific computer processing system.

### **Header**

Information placed in front of a message which ensures that the message is routed to its destination and that it can be opened and read by the receiving software.

### **HL7**

Health Level 7. An ANSI standard used to facilitate the electronic interchange of data in a healthcare environment.

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### **HTML**

Hypertext Markup Language. Commonly used to format Web pages.

### **Hypertext**

A system that enables links to be established between specific words or figures in a document to other text, tables or image allowing quick access to the linked items (such as on the World Wide Web).

### **ICH**

International Conference on Harmonization of .Technical Requirements for Registration of Pharmaceuticals for Human Use.

### **ICSR**

Individual Case Safety Report.

### **Information**

Any representation of knowledge such as facts, data, or opinions in any medium or form, including textual, numerical, graphic, cartographic, narrative, or audio-visual forms.

### **Information system (IS)**

A discrete set of information resources organized for the collection, processing, maintenance, transmission, and dissemination of information in accordance with defined procedures.

### **Infrastructure**

The basic support services for computing; the hardware, operating system, and network on which applications and data are stored and on which the database management systems run.

### **Interface**

A boundary across which two systems communicate; an information interchange path that allows parts of a computer, multiple computers, and external equipment to communicate or interact.

### **Internet**

The world-wide network of computers for accessing, sending, sharing, and transferring information between sites at different locations. It is uncontrolled and unadministered, and when you connect to the Internet, you actually become a part of it.

### **Interoperability**

The degree or extent to which diverse environments (hardware and software) are able to exchange information without loss of content, and in a manner transparent to the user.

### **Intranet**

A closed/private network which supports a distributed system and facilitates the distribution of information within an organization.

### **ISDN**

Integrated Services Digital Network; a relatively new technology which combines voice and digital network services in a single medium. ISDN makes it possible for communications carriers to offer their customers digital data services as well as voice connections through a single line.

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#### **ISO**

International Standards Organization - founded in 1946, it is the principal international standards-setting organization.

#### **Key**

The code to encrypt and decrypt files; most commonly as a pair called public key and private key.

#### **Legacy system**

An older computer system or application which remains in use after new versions or applications have been introduced, usually because it contains data on older projects for which it is not cost effective to transfer to the new systems or versions.

#### **Local Area Network (LAN)**

A data communication network which is limited to a building or a group of buildings in close proximity.

#### **Log-in Authentication**

A security mechanism which verifies the identification of a user who tries to access the network, or resources on the network. When you type your name and password, you are authenticated and allowed access.

#### **Mail Application Programming Interface (MAPI)**

A protocol used to transfer E-mail messages.

#### **Messaging**

The technology that enables messages to be sent by electronic mail. It includes directory services, allows composition of the message and addressing and transfer over the network.

#### **Migration**

The planned systematic transition from one application or system to another application or system.

#### **MIME**

Multipurpose Internet Mail Extension - this standard defines the message format for textual messages on the Internet.

#### **M2**

Multidisciplinary Group 2 (ESTRI) of ICH.

#### **Network**

A communication system which connects different computers and enables them to share peripherals such as printers, disk drives and databases. Users (clients) can access applications and databases connected by the network.

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#### **Network management**

The administration of a network so as to maximize its efficiency and productivity; this is usually divided into five categories of management - fault, configuration, security, performance, and accounting.

#### **Network operating system (NOS)**

An operating system which links software with other computers via a network, e.g., Microsoft Windows NT, Novell NetWare, etc.

#### **PDF**

Portable Document Format - a proprietary (Adobe Systems) de-facto standard for the electronic transfer of documents.

#### **PEM**

Privacy Enhanced Mail - an application which integrates a number of standards and is used for the secure electronic transfer of information.

#### **Personal Computer (PC)**

A general-purpose single-user microcomputer designed to be operated by one person at a time, e.g., IBM PC, Macintosh, etc.

#### **PGP**

Pretty Good Privacy - an application which integrates a number of standards and is used for the secure electronic transfer of information.

#### **Protocol**

A set of rules to which all IT companies and software products have to adhere; the language spoken between computers to help them exchange information.

#### **Prototyping**

The creation of a model and the simulation of all aspects of a product.

#### **Server**

The central computer (main processing unit) in a network which provides some service for other computers connected to it.

#### **SGML**

Standardized Generalized Markup Language. An ISO standard for describing structured information in a platform independent manner.

#### **S/MIME**

Secure MIME - an application which integrates a number of standards and is used for the secure electronic transfer of information.

#### **SMTP**

Simple Mail Transport Protocol; used for the transfer of messages (e-mail) on the Internet and some LANs and WANs.

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#### **Software**

Computer programs or applications. There are two principle types - system software, e.g., computer operating system or a utility program (sometimes called a driver) for printing; and application software, e.g., an accounts package or CAD program.

#### **Software platform**

The combination of a computer hardware type and its operating system (e.g. Intel Pentium / Windows 95).

#### **SQL**

Structured Query Language - software which facilitates database searching.

#### **Standard**

A technical specification which addresses a business requirement, has been implemented in viable commercial products, and, to the extent practical, complies with recognized standards organizations such as ISO.

#### **TCP/IP**

Transfer Control Protocol/Internet Protocol; the basic protocols which are used to transfer data on the Internet.

#### **TIFF**

Tag Image File Format - a CCITT standard for electronically storing images.

#### **Wide Area Network (WAN)**

A network, usually connected in serial lines, extending over areas larger than the LAN, and connecting several distant locations.

#### **Web page**

Any page on the World Wide Web. The page usually offers the reader ability to jump to other topics of interest.

#### **World Wide Web (WWW)**

Segment of the Internet offering point and click (hypertext) access to information, as text, image or sound, on an enormous number of topics from around the world.

#### **X.400**

Series of specifications published by CCITT.

#### **X.500**

Series of specifications published by CCITT.

#### **X.509**

Series of specifications published by CCITT.